

Remarks

Claim Objections

Claim 5 was objected to for lacking antecedent basis for the term "membrane unit" used in line 2 thereof. By the present amendment, the Applicant has established proper antecedent basis from claim 1 (from which claim 5 depends). As such, the Applicant believes the present objection to have been overcome.

Rejection under 35 USC 103

Claims 1-5, 8, 9, 13, 15, 18-21, 41, 42, 48, 51, 52 and 55-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita et al (US 6,371,971, hereinafter Tsugita) in view of Gianotti (US 5,836,962, hereinafter Gianotti). Claims 6, 10, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita in view of Gianotti as applied to claims above, and further in view of Daniel et al (US 5,814,064).

Independent claim 1 clearly recites a medical device made up of a membrane and reinforcement fibers coupled to the membrane such that a composite structure is formed by the fibers and membrane. Independent claims 48 and 55 recite that such medical device additionally includes a frame to attach the reinforcement fibers, and an elongated member (claim 48) or guide wire (claim 55) to facilitate movement of the composite structure. It is well-established that "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Miller*, 169 USPQ 597, 600 ((CCPA 1971), quoting *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970)). It is also bedrock law that such claim terms be construed in accordance with the specification. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990).

The present approach used by the Examiner in interpreting all of the terms in independent claims 1, 48 and 55 is incorrect, for while MPEP 2111 allows the Examiner a certain amount of latitude in claim term interpretation, it also unequivocally requires not an unmoored "broadest reasonable interpretation" but a broadest reasonable interpretation that is consistent with the specification. To that end, recourse to the specification is invaluable to determine the meaning

of the claims in the independent claims in general, and to the meaning of "composite structure" in particular. The original PCT specification clearly sets forth what the Applicant regards as the "composite structure" of the independent claims. For example, lines 22 through 31 on page 28 of the original specification note with particularity that two disparate members (in particular, a fiber reinforcement and a monolithic membrane matrix) are integrally combined to form a unitary "whole". Likewise, page 6, lines 3 through 4 notes for example the composite nature of the *membrane*, in that the membrane is of "thin, flexible" construction, while line 11 notes that "the membrane is made extremely thin", while page 7, line 11 gets to the essence of the membrane's composite nature when it states that "thin filaments . . . are embedded in the filter membrane" and that the "resulting composite membrane can have extreme flexibility and elasticity. . . ." More particularly, page 15, line 21, in conjunction with FIG. 5, shows that the membrane is a "thin sheet". Even more particularly, FIG. 6, in conjunction with page 6, lines 4 through 5, describes a medical device (a filter, in particular) made up of a sheet-like membrane. Tsugita and Gianotti (either alone or together) reveals no such structure where a membrane is reinforced with a fiber, wire or the like.

Tsugita teaches a vascular filter with either a mesh structure **25** (shown, for example, in FIGS. 1A through 1D, and described at column 7, line 15) or a membrane (described at column 7, lines 17 through 23) that may be continuous with holes drilled therein. There is no evidence that Tsugita contemplated forming the membrane out of a composite material, and to that end, the Examiner candidly admits in paragraph 7 of the Office Action that Tsugita does not disclose reinforcement fibers coupled to the membrane.

To rectify this deficiency in Tsugita, the Examiner introduces Gianotti, which teaches filaments **1** that can be wound together into a helical shape to be used as an endoprosthetic device. Each of the filaments **1** are made up of reinforcement fibers **4** embedded in matrix (called "support" by the patentee) **3** such that each of the individual filaments **1** is in turn a composite material made up of the fibers **4** and support **3**. Thus, while FIGS. 3 through 5 of Gianotti shows a composite structure, it is apparent that such composite structure is limited to a fiber-reinforced wire, cable or the like. Such composite structure is readily distinguished from

the claimed device, as there is nothing in the composite fiber of Gianotti to indicate that a composite structure involving a fiber reinforcing a membrane is formed. For example, there is not even a scintilla of evidence that Gianotti contemplated a membrane to which fiber reinforcement would cooperate. One of ordinary skill in the composite material art would recognize that the composite of Gianotti that makes up a reinforcing fiber that itself will be used to provide reinforcement of another material is in no way similar to the claimed fiber-reinforced membrane. Nor would one of ordinary skill in the composite material art be motivated to combine the high-cost reinforcement approach of Gianotti as an additional cost to reinforcing the membrane of Tsugita, as there is nothing in either of those references to suggest incorporating the device of the other.

"To establish a *prima facie* case of obviousness, three basic criteria must be met." MPEP 2143. MPEP 2143.03 states that one of the three criteria is that the combined references teach every aspect of the claimed invention. The various independent claims recite a composite membrane (claim 1) and a membrane-based medical device (claims 48 and 55). There is nothing in the combination of Tsugita and Gianotti to teach or suggest a membrane that is reinforced with a fiber coupled thereto in order to form a composite structure corresponding to those claims. As such, the Examiner must conclude that at least this component of the requirement for a *prima facie* case of obviousness has not been made out, and as such, the present rejection of independent claims 1, 48 and 55 can no longer be maintained.

Another of the requirements under MPEP 2143 is that there is some suggestion or motivation, either in the reference itself or in the knowledge available in the art, to modify that reference's teachings. MPEP 2143.01. Such motivation must be found in the prior art and not based on an applicant's disclosure. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). In carrying this burden, the Examiner must present a convincing line of reasoning as to why one of ordinary skill in the art would have found the claimed invention to have been obvious. *Ex parte Clapp*, 227 USPQ 972, 973 (PTOBPAI 1985). A rejection based on obviousness clearly must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. *In re Warner*, 154 USPQ 173, 178 (CCPA 1967). The Examiner

may *not*, because he or she may doubt that the invention is patentable, resort to speculation, unfounded assumptions, or hindsight reconstruction to supply deficiencies in his required factual basis. *Id.*

In the present rejection, the Examiner at most has disparate references that provide no motivation between them to combine the composite wire of one (Ginaotti) with the membrane of the other (Tsugita). In fact, the only place such motivation is provided is in the Applicant's disclosure, and such rationale amounts to impermissible hindsight in violation of MPEP 2142. As such, the Examiner's assertion that the combination of Tsugita and Gianotti renders independent claims 1, 48 and 55 obvious is merely conjecture. It is well-established USPTO practice that conjecture or speculation is not a substitute for objective evidence, and that such conjecture or speculation is insufficient for the Examiner to discharge his or her burden to establish a *prima facie* case. *Graham v. John Deere*, 148 USPQ 459 (1966).

CONCLUSION

Having shown that aspects of the present rejection based on Tsugita in view of Gianotti run afoul of at least two of the three components of the tripartite test for *prima facie* obviousness, the Applicant respectfully submits that the present rejection for independent claims 1, 48 and 55, as well as all of the claims that depend from them, be withdrawn. Furthermore, the Applicant respectfully requests that a finding of patentability for all of the claims be issued.

The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,
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